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FEDERAL AFFAIRS DEPARTMENT

VIA ELECTRONIC MAIL

June 21, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm.1061
Rockville, MD 20852

Re: Study on Making Prescription Pharmaceutical Information Accessible to Blind and Visually Impaired Individuals, Docket No. 2004N-0221

The American Academy of Ophthalmology—which represents more than 17,000 ophthalmologists in the United States—is pleased to submit the following comments regarding the above docket item. In summary, the Academy believes that a study addressing mechanisms for relaying prescription drug information to blind and visually impaired individuals could benefit by clarifying the definitions, the populations being addressed, and examining the accessability factors relevant to each group. The Academy has information regarding a number of ways that essential drug information can be presented based on our own experience with this population.

Introduction

"Blind" to the sighted population means no vision; "blind" in the context of statistics, however, means "legally blind," which is defined as visual acuity $\leq$ 20/200 or a visual field $\leq$ 15 degrees. Medicare recognizes visual impairment to include: moderate impairment, which is best visual acuity of 20/70; severe impairment, which is best visual acuity of $\leq$ 20/200 or a visual field of 15 degrees (the parameters of "legal blindness"); profound impairment, which is visual acuity < 20/400 to and including 20/1000; near-total impairment which is residual vision < 20/1000; and total impairment is complete blindness.

Reading is a function primarily of visual acuity; individuals whose "legal blindness" is defined by loss of visual field rather than by acuity may be able to read standard print in spite of being legally blind. Conversely those with visual acuities better than "legal blindness" may be unable to read standard print. Therefore "legal blindness" is not a useful term for this discussion, as it does not correlate with function, so the term "visual impairment" will be used to designate anyone with any level of residual vision and when it is relevant the degree of visual impairment will be indicated.

A. Information About the Population of Interest

1. What is known about the population who are blind and visually impaired?

The vast majority of visually impaired people in the U.S.A. are seniors. It is estimated, for example, that in the state of Michigan there are in the range of 3,000 blind and visually

impaired children and adolescents (to age 26), approximately 16,000 blind and severely visually impaired adults (ages 26 and 55), and an estimated 100,000 visually impaired seniors (age 65 and older). Seniors are the fastest growing population in the country, are more likely than younger people to be on multiple medications, and are more likely than younger people to have co-morbid conditions such as hearing loss and arthritis. Furthermore, many seniors with no ophthalmic disease and normal visual acuities lose some contrast sensitivity, which in itself makes reading fine print problematic. Because of the disease processes causing visual impairments in younger people, they may be more likely than seniors to have profound, near-total and total impairments.

2. Is there an appropriate way to divide the population into subpopulations?

Dividing the population may be beneficial. People of any age who have profound, near total, or total visual impairments but who retain good hearing would benefit most from audio equipment. Braille would of course be useful for the diminishing numbers who read it. Those with moderate to severe impairments and loss of contrast sensitivity, however, particularly those with comorbid hearing impairments, would benefit most from high contrast, large print materials.

B. Information About the Use of Prescription Medication Information by People who are Blind and Visually Impaired.

1. How do people who are blind and visually impaired get their prescription drug information?

Those with sufficient contrast sensitivity who have access to appropriate magnification devices and training in their use may be able to read their prescription drug information. Otherwise, someone else reads it to them, or they do without the information. A handful of those with sufficient hearing and sufficient funds may have audio devices.

2. What factors may be important in addressing this issue?

(1) Loss of contrast sensitivity among many seniors, including those with visual acuities in a normal range, requiring high contrast print or markings.
(2) Moderate loss of visual acuity, requiring enlarged print.
(3) Severe loss of visual acuity, requiring audio devices.
(4) Loss of hearing among the elderly, requiring extra loud audio devices or other alternatives.
(5) Multiple medications among seniors, requiring distinguishing them one from another.
(6) Complicated dosage regimens with multiple medications.
(7) Combination of difficult material to read and limited vision decreases access.
(8) Arthritic fingers and tactile loss among seniors make access to medications difficult even if they have access to and understand the correct information.

3. How can essential drug information be communicated.?

(1) High contrast in labels, markings, and all printed materials
(2) Large print materials

(3) Audio methods
   a. "Talking" devices
   b. Easy access to information by phone: easy phone number and medication code
(4) Provide a large picture or photo of each pill, with use (ie. heart, cholesterol) and dosage in large print on a separate card to accompany each prescription. This would be particularly helpful for those with multiple medications.
(5) Code the caps:
   a. Color-code caps by dose (eg. red = 2/day, blue = 3/day)
   b. Imprint caps with a large number representing daily dose
(6) Provide different container colors and/or sizes.
(7) Write the inserts in straightforward consumer-friendly language.
(8) To promote accurate dosing:
   a. Offer large-size weekly pill organizers for purchase at the pharmacy, with lids that can be opened by arthritic fingers.
   b. Cut pills in half before dispensing, when indicated.
(9) For those who are computer literate and use adaptive computer technology, posting medication information on a website in large print would be excellent. However, this does not encompass a majority of the current senior population.

4. Are There Data Associating Medication Errors with Blindness and Visual Impairment?

We are not aware of any published studies or data, but many anecdotal reports of errors come from occupational therapists and others who work with visually impaired seniors in their homes, including:
(1) Confusion regarding identity, purposes, and dosages of medications
(2) Mixing of different medications in the same bottle after being spilled
(3) Disregarding medications because of inability to determine how to take them
(4) Dosing by guess, eg. "I just take them all a couple times a day."

Data does suggest that inability to manage medications is a leading cause of admission to assisted living facilities and that among residents of nursing homes, many are found to have unreported low vision. The interaction of age, low vision, medication needs, and medication management by individuals clearly warrants investigation and attention.

C. Information About Existing and Emerging Technologies

1. What assistive technologies are currently used by people who are blind and visually impaired? In what setting?

(1) A few people use audio devices.
(2) Those with appropriate magnification devices, including magnifiers and video magnifiers (closed circuit TVs, CCTVs), use them for reading medication labels and sometimes for reading inserts.
(3) Those with computer access may look up general information on the drug.

2. What percentage of the population uses these technologies?

Very few, but the use of magnification devices is increasing.

3. Are there data on the effectiveness of these technologies?

There is no question that CCTVs, for example, are effective in allowing access to reading materials to people with moderate, severe, and even profound visual impairments, if the print is clear and not so small to begin as to be distorted with high magnification, (e.g. the letters in very small type often touch each other; when magnified two letters may appear as one). The same is true of non-electronic magnifiers. Audio devices have proven effective for other uses, e.g. books on tape.

4. Do these technologies contribute to an increase or decrease in medication errors reported among people who are blind and visually impaired?

Anecdotally, a decrease. People who can actually read medication labels and instructions are less likely to make errors. I have no experience with the audio devices, but I would expect the same advantage for those who do not have impaired hearing.

5. What is the cost of these technologies?

Magnifiers range from $10 to $150. CCTVs range from $350 to $3,000. I believe the audio devices are several hundred dollars. A distinction in terms of impact on an individual's budget is that the audio devices have a unique application whereas the magnification tools can be used for many purposes.

6. Who are the primary purchasers of these technologies? Are they subsidized by government of private programs?

The primary purchasers are seniors because they are the primary group with visual impairments. These technologies are not subsidized for seniors with moderate visual impairments. A state commission for the blind may purchase magnifiers and lower cost CCTVs for seniors with severe and profound visual impairments. Most seniors, however, must purchase their own devices. Medicare considers these devices the equivalent of glasses, and therefore they are not a covered benefit.

7. What are the barriers to use of these technologies?

The single biggest barrier is lack of awareness of them. The second is lack of training in their use. The third is cost. With regard to computers, it is lack of a computer, lack of awareness of adaptive features, and lack of adaptive computer skills.

8. What is the practicability of these assistive devices?

The magnification devices and CCTVs are very practical. Matching the senior to the most appropriate device is usually necessary, so simply purchasing a device does not represent successful use. Most people requiring magnification devices benefit greatly from vision rehabilitation training to assure successful application of devices to tasks. The audio devices may be less practicable because they are single purpose.

9. What are the most effective resources for conveying information about these assistive technologies to blind and visually impaired individuals?

(1) Ophthalmologists and optometrists.
(2) Geriatricians, internists, family practitioners
(3) Geriatric nurses
(4) State commissions for the blind and visually impaired
(5) Private organizations for the blind and visually impaired
(6) Senior centers

The Academy wishes to make clear that the above observations only represent our overall comments in response to the FDA's May 20 *Federal Register* announcement. Nothing contained herein should be construed as an endorsement of any specific program, device, pharmaceutical, or policy initiative. Further, the Academy believes that the FDA should carefully examine the cost/benefit implications of any technology or policy initiatives in this area.

The Academy hopes that the FDA finds these comments and observations of value. Should you have any questions, please do not hesitate to contact me or Dr. Lylas Mogk, MD at (313)-824-4800 or via email at LMogk@aol.com.

Sincerely,

William L. Rich III, MD
Secretary for Federal Affairs